UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,897	03/15/2004	Jean-Louis Dasseux	9196-032-999	4097

20583 7590 08/03/2005

JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 08/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/801,897	DASSEUX ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *53-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *53-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *20040525*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

The paper copy of the sequence listing filed March 15, 2005, which contains 254 sequences, is not the same as the computer readable form copy of the sequence listing obtained from one of the parent applications, which contains 258 sequences. In addition, the sequence listing statement made in section 8 of the continuation request form is incomplete because it does not identify the serial number and filing date of the prior application from which is to be obtained the computer readable form of the sequence listing.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing and/or a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 18.21(e) and/or 1.825(a) and (b).

2. In the priority claim inserted at page 1, line 1, of the specification by the preliminary amendment filed March 15, 2004, the status of parent application 09/865,989 should be updated.

3. Claims 53-83 are objected to because of the following informalities: In claim 53, the recitation of the "pharmaceutically acceptable salt thereof" at line 5, and the recitation of the "salt thereof" at line 24, appear to be redundant. The definitions of "R" in claims 53 and 56 which refer to C_1 alkenyl and C_1 alkynyl groups are an obvious typographic error because

unsaturated alkenyl and alkynyl bonds require at least 2 carbon atoms. Appropriate correction is required.

4. Applicant is advised that should claim 53 be found allowable, claim 59 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 59 is identical in scope with claim 53, because claim 59 merely repeats a limitation found at claim 53, lines 2-3.

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 53-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No. 6,734,169 in view of Sepetov et al (U.S. Patent No. 5,470,753), Stig et al (U.S. Patent No. 5,464,821), Nutt et al (U.S. Patent No. 5,204,328), or Theodore et al (U.S. Patent No. 5,578,287). The '169 patent claims ApoA-I agonists of formula (I) which significantly overlap the ApoA-I agonists of formula (I) of the instant claims, and claims agonists which can comprise substituted amide linkages and amide

isosteres. The agonists of both sets of claims form amphipathic α-helices in the presence of lipids, and are used for the same pharmaceutical purpose of treating dyslipidemia. The '169 patent does not claim any specific agonist in which a substituted amide linkage or an amide isostere is present. Sepetov et al disclose substituted reduced peptide bonds having the structure $-CH_2-NH-$ for peptides bonds in order to extend the half-life of the resulting peptide in vivo due to resistance to metabolic breakdown or protease activity. See column 8, lines 3-11. Stig et al teach introducing ketomethylene and methylsulfide bonds in place of peptide bonds in order to enhance the stability and potency of the resulting peptides. See column 6, lines 50-53. Nutt et al teach the use of N-alkylated amino acids to rigidify peptide conformation and confer resistance towards enzymatic degradation. See column 3, lines 63-68. Theodore et al disclose the general strategy of using N-methyl amino acids in peptides to improve serum stability of the peptides with respect to enzymatic action. See column 13, lines 53-56, and column 16, lines 33-34. It would have been obvious to one of ordinary skill in the art to modify the claimed agonists of the '169 patent through the use of substituted amide linkages or the use of amide isosteres as taught by Sepetov et al, Stig et al, Nutt et al, and Theodore et al because such modifications are claimed by the '169 patent and because Sepetov et al, Stig et al, Nutt et al, and Theodore et al suggest that such modifications would have the benefit of increasing the resistance of the agonists to in vivo proteolysis.

7. Claims 53-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-40 of U.S. Patent No. 6,265,377 in view of Sepetov et al (U.S. Patent No. 5,470,753), Stig et al (U.S. Patent No. 5,464,821), Nutt et al (U.S. Patent No. 5,204,328), or Theodore et al (U.S. Patent No. 5,578,287). The '377 patent claims

ApoA-I agonists of formula (I) which significantly overlap the ApoA-I agonists of formula (I) of the instant claims, and claims agonists which can comprise substituted amide linkages and amide isosteres. The agonists of both sets of claims form amphipathic α-helices in the presence of lipids, and are used for the same pharmaceutical purpose of treating dyslipidemia. The '377 patent does not claim any specific agonist in which a substituted amide linkage or an amide isostere is present. Sepetov et al disclose substituted reduced peptide bonds having the structure $-CH_2-NH-$ for peptides bonds in order to extend the half-life of the resulting peptide in vivo due to resistance to metabolic breakdown or protease activity. See column 8, lines 3-11. Stig et al teach introducing ketomethylene and methylsulfide bonds in place of peptide bonds in order to enhance the stability and potency of the resulting peptides. See column 6, lines 50-53. Nutt et al teach the use of N-alkylated amino acids to rigidify peptide conformation and confer resistance towards enzymatic degradation. See column 3, lines 63-68. Theodore et al disclose the general strategy of using N-methyl amino acids in peptides to improve serum stability of the peptides with respect to enzymatic action. See column 13, lines 53-56, and column 16, lines 33-34. It would have been obvious to one of ordinary skill in the art to modify the claimed agonists of the '377 patent through the use of substituted amide linkages or the use of amide isosteres as taught by Sepetov et al, Stig et al, Nutt et al, and Theodore et al because such modifications are claimed by the '377 patent and because Sepetov et al, Stig et al, Nutt et al, and Theodore et al suggest that such modifications would have the benefit of increasing the resistance of the agonists to in vivo proteolysis.

8. Claims 53-83 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-54 of U.S. Patent No. 6,037,323 in view of

Sepetov et al (U.S. Patent No. 5,470,753), Stig et al (U.S. Patent No. 5,464,821), Nutt et al (U.S. Patent No. 5,204,328), or Theodore et al (U.S. Patent No. 5,578,287). The '323 patent claims ApoA-I agonists of formula (I) which significantly overlap the ApoA-I agonists of formula (I) of the instant claims, and claims agonists which can comprise substituted amide linkages and amide isosteres. The agonists of both sets of claims form amphipathic α-helices in the presence of lipids, and are used for the same pharmaceutical purpose of treating dyslipidemia. The '323 patent does not claim any specific agonist in which a substituted amide linkage or an amide isostere is present. Sepetov et al disclose substituted reduced peptide bonds having the structure $-CH_2-NH-$ for peptides bonds in order to extend the half-life of the resulting peptide in vivo due to resistance to metabolic breakdown or protease activity. See column 8, lines 3-11. Stig et al teach introducing ketomethylene and methylsulfide bonds in place of peptide bonds in order to enhance the stability and potency of the resulting peptides. See column 6, lines 50-53. Nutt et al teach the use of N-alkylated amino acids to rigidify peptide conformation and confer resistance towards enzymatic degradation. See column 3, lines 63-68. Theodore et al disclose the general strategy of using N-methyl amino acids in peptides to improve serum stability of the peptides with respect to enzymatic action. See column 13, lines 53-56, and column 16, lines 33-34. It would have been obvious to one of ordinary skill in the art to modify the claimed agonists of the '323 patent through the use of substituted amide linkages or the use of amide isosteres as taught by Sepetov et al, Stig et al, Nutt et al, and Theodore et al because such modifications are claimed by the '323 patent and because Sepetov et al, Stig et al, Nutt et al, and Theodore et al suggest that such modifications would have the benefit of increasing the resistance of the agonists to in vivo proteolysis.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Bruce Campell can be reached at (571) 272-0974. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

July 28, 2005